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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,316

03/17/2006

Robert Jongejan

27233U

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34375 7590 12/24/2008

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EXAMINER

BLIZZARD, CHRISTOPHER JAMES

ART UNIT

PAPER NUMBER

4185

MAIL DATE

DELIVERY MODE

12/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,316	Applicant(s) JONGEJAN ET AL.	
	Examiner CHRISTOPHER BLIZZARD	Art Unit 4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/17/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/16/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-5, 7, 8, 10, 13-22 and 25** are rejected under 35 U.S.C. 102(b) as being anticipated by **Wolf (US 5,809,997)**.

Regarding claim 1, Wolf discloses a compliance monitor for a drug delivery device for administering a drug, comprising; a switch, in the form of a strain gauge dynamic sensing arm (1555), actuatable by a user on delivering a dose from the device (Abstract); a sensor (1560) for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose (column 19, lines 21-41); and a processor (1540) coupled to the switch (1555) and the sensor (1560) (fig. 16) for recording whether or not the device was properly positioned when the switch was actuated.

Regarding claim 2, Wolf discloses a compliance monitor which does not affect the normal operation of the drug delivery device (column 3, lines 24-27).

Regarding claim 3, Wolf discloses a compliance monitor (1200) which is removably attachable to the drug delivery device(1210) (column 17, lines 7-16).

Regarding claim 4, Wolf discloses a compliance monitor comprising a clock coupled to a processor (605) and in which the time of actuation of the switch is recorded (column 6, lines 25-30).

Regarding claim 5, Wolf discloses a compliance monitor wherein proper positioning of the drug delivery device is positioning in contact with or relative to the user's mouth, nose or skin (column 15, lines 58-60).

Regarding claim 7, Wolf discloses a compliance monitor wherein the drug delivery device is for oral administration of the drug (column 15, lines 58-60).

Regarding claim 8, Wolf discloses a compliance monitor wherein the drug delivery device is an inhaler operated by the user depressing a pressurized canister (1590) containing the drug, and wherein the switch is a pressure-operated switch (1555) actuatable as the user depresses the canister (figs. 17b and 17c).

Regarding claim 10, Wolf discloses a compliance monitor in which the sensor (425) is a temperature sensor, in the form of a thermistor, for sensing body temperature (columns 15,16; lines 58-67, 1-5).

Regarding claim 13, Wolf discloses a compliance monitor according in which a change in an output of the sensor characteristic of correct use of the drug delivery device is used to determine whether the device was properly positioned when the dose was delivered (column 15, lines 55-65).

Regarding claim 14, Wolf discloses a compliance comprising an output (415) for downloading data to a docking station or a computer (fig. 10).

Regarding claim 15, Wolf discloses a compliance monitor in which the data comprises a compliance record of use of the drug delivery device, including a record of whether the sensor output indicates that the device was properly positioned on each occasion that a dose has been delivered (column 3, lines 58-69) (column 15, 58-60).

Regarding claim 16, Wolf discloses a docking station (2030) for use with a compliance monitor (fig. 20).

Regarding claim 17, Wolf disclose a compliance monitor with computer-readable medium carrying a computer program for programming a general purpose computer to receive and process data downloaded from a compliance monitor (column 6, lines 41-50).

Regarding claim 18, Wolf discloses a compliance monitor with a drug delivery device (Abstract).

Regarding claim 19, Wolf discloses a method of using a compliance monitor to monitor use of a drug delivery device for administration of a drug, comprising the steps of: determining when a user operates the device to deliver a dose of the drug (column 1, lines 11-20); sensing whether the device is properly positioned in contact with or relative to the user's body when the dose is delivered (column 15, lines 55-60); and recording for each operation of the device whether or not the device was properly positioned (column 16, lines 2-5).

Regarding claim 20, Wolf discloses a method comprising the step of determining and recording the time of each operation of the device (column 1, lines 16-17).

Regarding claim 21, Wolf discloses a method in which the drug delivery device is for oral administration of the drug and proper positioning of the device is proper positioning in the user's mouth (column 15, lines 58-60).

Regarding claim 22, Wolf discloses a method comprising a step of downloading recorded data from the compliance monitor to a docking station or a computer to allow a compliance record to be reviewed (fig. 20) (column 6, lines 41-45).

Regarding claim 25, Wolf discloses a compliance monitor wherein the drug delivery device is for oral administration by inhalation (column 15, 55-60).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Wolf (US 5,809,997)** in view of **Reinhold (US 7,073,499 B1)**.

Regarding claim 6, Wolf fails to disclose a compliance monitor wherein the drug delivery device is for topical administration of the drug.

However, Reinhold et al. discloses a drug delivery device, in the form of an inhaler, for topical administration of a drug (column 14, lines 61-63).

4. It would have been obvious to one of ordinary skill in the art to modify the invention of Wolf to include a drug delivery device as taught by Reinhold since doing so

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would allow the invention to be used by patients with a wider range of medication needs.

Regarding claim 9, Wolf fails to disclose a compliance monitor wherein the drug delivery device is selected from the group consisting of a dry powder inhaler, a pressurized metered dose inhaler and a nebuliser.

However, Reinhold teaches the similarities of drug delivery devices, including dry powder inhalers, pressurized metered dose inhalers and nebulisers (column 1, lines 25-28).

5. It would have been obvious to one of ordinary skill in the art to modify the invention of Wolf to use various drug delivery devices as taught by Reinhold since doing so would allow the invention to be used by patients with a wider range of medication needs.

6. **Claims 11 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Wolf (US 5,809,997)** in view of **Trueba (US 6,684,880 B2)**.

Regarding claim 11, Wolf fails to disclose a compliance monitor in which a sensor is a light sensor for sensing when the sensor is covered.

However, Trueba discloses a compliance monitor with a light sensor for sensing when the sensor is covered (column 13, lines 28-31).

7. It would have been obvious to one of ordinary skill in the art to modify the invention of Wolf to include a light sensor as taught by Trueba since doing so would provide a simple way of determining if the invention was properly used column 13, lines 28-31).

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Regarding claim 12, Wolf fails to disclose a compliance monitor in which the sensor is a conductivity sensor for sensing body conductivity.

However, Reinhold discloses a compliance monitor with one or more sensors for determining proper use of device.

8. It would have been obvious to one of ordinary skill in the art to modify the invention of Wolf to include a sensor as taught by Reinhold, and for the sensor to be a conductivity sensor, since doing so would provide a simple way of determining if the invention was properly used.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the applicant's claimed and disclosed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Blizzard whose telephone number is (571)-270-7138. The examiner can normally be reached on Monday-Thursday 7:30 AM - 6:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571) 272-4797.

12/18/2008
/C. B./
Examiner, Art Unit 4185
/Terrell L McKinnon/
Supervisory Patent Examiner, Art Unit 4185